Eudamed and CTIS: Lessons from EudraCT

Transparency is a pre-requisite for effective public interventions in pharmaceutical policy. It is also essential to improving access to health technologies, most notably medicines, vaccines and diagnostic tools and devices. Two European databases currently being developed and due to go live at the start of 2022, the Clinical Trials Information System (CTIS) and the European Databank on Medical Devices (Eudamed), could significantly improve the quantity, quality and transparency of evidence on the efficacy and harms of drugs and medical devices for many years to come.

Collectively, they would allow the European Union (EU) to better contribute to the global effort to fight COVID-19 through initiatives such as the COVID-19 Technology Access Pool (C-TAP). They could also be instrumental in the fulfilment of the TRIPS waiver currently under discussion (albeit opposed by the European Commission).Information on efficacy and safety of medical devices, especially diagnostics, would be critical for the development of a global test and treat strategy which could go a long way to ending the pandemic.

However, CTIS and Eudamed will only fulfil these promises if they are well designed, effectively run, and supported by additional compliance-boosting measures and, more importantly, buy in from private manufacturers, regulatory authorities and policy makers.

This report sets out ten simple, low-cost and high-yield regulatory approaches that the European Medicines Agency (EMA) and the European Commission can take to improve the quantity, quality and transparency of data on CTIS and Eudamed. Each recommended approach draws on lessons learnt from the current European trial registry EudraCT, which has been in operation since 2004 as well as specific requirements to medical devices efficacy and safety.

The recommendations listed in this report are structured chronologically into recommendations for the initial design phase and the subsequent launch phase for both CTIS and Eudamed.

Download the report and recommendations here (PDF)